Data Evaluation Report on the Acute Toxicity of Saflufenacil to Bluegill Sunfish (*Lepomis macrochirus*)

PMRA Submission Number: 2008-0431
PMRA Document ID: 1547215 EPA MRID Number: 47127905

Data Requirement:	PMRA Data Code	9.5.2.2
	EPA DP Barcode	349851
	OECD Data Point	IIA 8.2.1.2
	EPA MRID	47127905
	EPA Guideline	OPPTS 850.1075 (72-1c)

Test material: BAS 800 H **Purity:** 93.8%
Common name: Saflufenacil
Chemical name:
IUPAC: N`[2-chloro-4-fluoro-5(3-methyl-2,6-dioxo-4-(trifluormethyl)-3,6-dihydro-1(2H)-pyrimidinyl)benzoyl]-N-isopropyl-N-methylsulfamide
CAS name: Not reported
CAS No.: 372137-35-4
Synonyms: None reported

Aviva L. Kafka

Primary Reviewer: Aviva L. Kafka **Signature:**
Staff Scientist, Cambridge Environmental Inc. **Date:** 03/28/08

Secondary Reviewer: Teri S. Myers **Signature:** Teri S Myers
Staff Scientist, Cambridge Environmental Inc. **Date:** 04/04/08

Primary Reviewer: Anita Pease **Date:** 06/09/09 Apease 6/9/09
Senior Biologist, U.S. EPA

Secondary Reviewer: Ann Lee **Date:** 06/09/09
HC-PMRA-EAD

Secondary Reviewer: Farzad Jahromi **Date:** 06/09/09
DEWHA-APVMA

Company Code	BAZ
Active Code	SFF
Use Site Category:	13 (terrestrial feed crops) and 14 (terrestrial food crops)
EPA PC Code	118203

CITATION:

Jatzek, J. 2005. BAS 800 H: Acute Toxicity Study on the Bluegill Sunfish (*Lepomis macrochirus*) in a Static System over 96 Hours. Unpublished study performed by Experimental Toxicology and Ecology, Ludwigshafen/Rhein, Germany. Laboratory report number 14F0414/015147. Study sponsored by BASF Aktiengesellschaft. Final report prepared December 21, 2005.

DISCLAIMER: This document provides guidance for EPA and PMRA reviewers on how to complete a data evaluation record after reviewing a scientific study concerning the acute toxicity of a pesticide to fish. It is not intended to prescribe conditions to any external party for conducting this study nor to establish absolute criteria

APPENDIX I: COPY OF REVIEWER'S TWA CALCULATIONS:

Time-Weighted Average (TWA) Concentrations

Nominal (mg ai/L)	0 Hrs	% of Nom.	48 Hrs	% of Nom.	96 Hrs	% of Nom.	TWA (mg ai/L)	% of Nom.
Negative Control	<0.001	N/A	<0.001	N/A	<0.001	N/A	<0.001	N/A
120	114.1	95.1	107.5	89.6	104.1	86.8	108.30	90.3
120	114.3	95.3	108.4	90.3	104.9	87.4	109.00	90.8
120	111.8	93.2	107	89.2	100.7	83.9	106.63	88.9
						Average	**107.98**	

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I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: This study was conducted following guidelines outlined in the OECD Guideline for Testing of Chemicals No. 203, July 1992 ("Fish Acute Toxicity Test"), EEC directive 92/96, Annex V, C1, as well as in the EPA Guideline "Pesticide Assessment Guidelines, subdivision E, Hazard Evaluation Wildlife and Aquatic Organisms, U.S. Environmental Protection Agency, Washington DC, 72-1, 1982 and the U.S. Environmental Protection Agency Series 850- Ecological Effects Test Guidelines, OPPTS No. 850-1075 (draft, 1996), *Fish Acute Toxicity Test, Freshwater and Marine.* The following deviations from OPPTS 850.1075 were noted:

1. As recommended in the 850 guidelines, chemical analysis of the dilution water was not reported for the following parameters: particulate matter, chemical oxygen demand (COD), total organic carbon (TOC), boron and fluoride, residual chlorine, un-ionized ammonia, metals, pesticides, and PCBs.
2. Adult fish (27 months old) with a mean weight of 4.10 g were tested; however, the 850.1075 guideline recommends that juvenile fish <3.0 g be used.
3. The length of the fish exceeds the OECD recommended length of 2.0 $\pm$ 1.0 cm for bluegill sunfish.
4. The concentrations of dissolved oxygen decreased to a range of 59% saturation in two of the test vessels at 48 hours; therefore, the tanks were slightly aerated during the last two days of exposure. Although dissolved oxygen fell below the 60% saturation standard specified in the 850.1075 guideline, and aeration of the tanks was necessary, measured concentrations of Saflufenacil at 48 and 96 hours appeared to be within the acceptable range of nominal concentrations.

These deviations do not affect the acceptability or scientific soundness of this study.

COMPLIANCE: Signed and dated No Data Confidentiality, GLP and Quality Assurance statements were provided. This study was conducted in accordance with the OECD Principles of Good Laboratory Practice and the GLP Principles of the German "Chemikaliengesetz" (Chemicals Act), which meet the United States Environmental Protection Agency Good Laboratory Practice Standards [40 CFR Part 60 (FIFRA) and Part 792 (TSCA)], with the following exception: recognized differences exist between the GLP Principles/Standards of OECD and the Principles/Standards of FIFRA and TSCA.

A. MATERIALS:

1. Test material BAS 800 H (Saflufenacil)

Description: Solid/light beige

Lot No./Batch No. : COD-000515

Purity: 93.8%

Stability of compound

concentration. As TWA concentrations are more indicative of actual concentration levels, they were reported in the Executive Summary and Conclusions sections of this DER. TWA concentrations were calculated using the following equation:

$$C_{TWA} = \frac{\left(\frac{C_1 + C_0}{2}\right)(t_1 - t_0) + \left(\frac{C_2 + C_1}{2}\right)(t_2 - t_1) + \left(\frac{C_{n-1} + C_2}{2}\right)(t_{n-1} - t_2) + \left(\frac{C_n + C_{n-1}}{2}\right)(t_n - t_{n-1})}{t_n}$$

where:
C_{TWA} is the time-weighted average concentration,
C_j is the concentration measured at time interval j (j = 0, 1, 2,...n)
t_j is the number of hours (or days or weeks, units used just need to be consistent in the equation) of the test at time interval j
(e.g., t_0 = 0 hours (test initiation), t_1 =48 hours, t_2 =96 hours)

All test batches were present as clear solutions over the exposure period according to visual inspection.

It should be noted that adult fish (27 months old) with a mean weight of 4.10 g were tested, whereas the 850.1075 guideline specifies the use of juvenile fish <3.0 g. The guideline requires testing with juvenile fish because they are generally more sensitive to pesticides than adult fish; however, the results of the companion Rainbow Trout acute toxicity study with Saflufenacil show no mortality or sublethal effects at exposure concentrations similar to those tested in this Bluegill Sunfish acute study. Given that no acute mortality and/or sublethal effects were observed in juvenile Rainbow Trout and adult Bluegill Sunfish at similar exposure concentrations, it appears that use of adult Bluegill Sunfish does not affect the scientific soundness of the acute study.

In addition, dissolved oxygen dropped to <60% saturation in two test vessels at 48 hours; therefore, the tanks were slightly aerated during the last two days of exposure. Although dissolved oxygen fell below the 60% saturation standard specified in the 850.1075 guideline, and aeration of the tanks was necessary, measured concentrations of saflufenacil at 48 and 96 hours appeared to be within the acceptable range of nominal concentrations. The reviewer agrees with the study author that the decrease in dissolved oxygen is considered to have no effect on the validity and the results of the study, because no adverse effects and no mortality were observed in the test vessels with decreased oxygen content, and measured exposure concentrations in these test vessels were provided.

The experimental start and completion dates were October 29 and November 4, 2005, respectively.

G. CONCLUSIONS:

This study is scientifically sound and is classified as ACCEPTABLE to U.S. EPA, FULLY RELIABLE to PMRA, and FULLY RELIABLE WITH RESTRICTION to APVMA. The 96-hour LC_{50} was >108 mg a.i./L. Due to a lack of treatment-related mortality or sub-lethal effects, the NOAEC was 108 mg a.i./L. Based on the results of this study, Saflufenacil would be classified as practically nontoxic to Bluegill Sunfish (*Lepomis macrochirus*) on an acute toxicity basis.

LC_{50}: >108 mg a.i./L (TWA) 95% C.I.: N/A
NOAEC: 108 mg a.i./L (TWA) Probit Slope: N/A
EC_{50}: >108 mg a.i./L (TWA)
Endpoint(s) Affected: None

B. STUDY DESIGN:

1. Experimental Conditions

a. Range-finding study: Test concentrations were selected on the basis of the non-GLP range finding part of the study. The LC_{50} range derived from 96-hour range finding was >100 mg/L, therefore a nominal concentration of 120 mg/L was selected to ensure that the analytical recovery is above the limit test value of 100 mg/L.

b. Definitive Study

Table 1: Experimental Parameters

Parameter	Details	Remarks *Criteria*
Acclimation Period: Conditions: (same as test or not) Feeding: Health: (any mortality observed)	 14 days Same Ecostart 17 (Bio Mar), ad libitum, and frozen brine shrimp (artemia) generally on workdays 0% mortality	Food supplier was Kofu Tiernahrung, Betriebsstatte Wesel, Hafenstr. 11-13, 46483 Wesel, Germany. *The recommended acclimation period is a minimum of 14 days; OECD guideline recommends a minimum of 12 days. Pretest mortality should be < 3% 48 h. prior to testing. OECD pretest mortality criteria: >10% = rejection of entire batch; ≥ 5 and ≤ 10% = continued acclimation for 7 days; <5% = acceptable.*
Duration of the test	96 hours	*The recommended test duration is 96 hours.*
Test condition Static/flow-through Type of dilution system - for flow-through method. Renewal rate for static renewal	 Static N/A N/A	*A reproducible supply of toxicant is recommended. Consistent flow rate is usually 5-10 vol/24 hours; meter systems should be calibrated before and after study and checked twice daily during test period.*
Aeration, if any	None over the first 48 hours, slight aeration during the last days of exposure, because the oxygen content after 48 hours was decreased to a range of 59% saturation.	The concentration of the test substance was reduced by test end (84 – 87% of nominal at 96 hours); however, recoveries were well within the acceptable range.

Table 3: Effect of Saflufenacil on Mortality of Bluegill Sunfish (*Lepomis macrochirus*).

Treatment (mg a.i./L) measured* and (nominal) concentrations	No. of fish at start of study	Observation period					
		24 Hours		72 Hours		96 Hours	
		No Dead	% mortality	No Dead	% mortality	No Dead	% mortality
Control (dilution water only), if used	10	0	0	0	0	0	0
Solvent control, if used	10	0	0	0	0	0	0
108 (120)	10	0	0	0	0	0	0
109 (120)	10	0	0	0	0	0	0
107 (120)	10	0	0	0	0	0	0
NOAEC	120 mg a.i./L (nominal)						
LC_{50}	>120 mg a.i./L (nominal)						
Positive control, if used mortality: LC_{50}:	N/A						

*Measured concentrations represent the TWA for each replicate. The overall measured concentration represents the arithmetic average of these three TWA concentrations.

B. NON-LETHAL TOXICITY ENDPOINTS:

There were no sub-lethal effects in the control or treatment levels.

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Parameter	Details	Remarks *Criteria*
Water parameters: Hardness	Approx. 1mmol/L = 100 mg/L $CaCO_3$	Conductivity was approximately 250 µS/cm (at 25°C). The tap water was regularly assayed for chemical contaminants by the municipal authorities of Frankenthal and the Technical Services of BASF Aktiengesellschaft as well as for presence of microbes by a contract company. Based on the analytical findings, the drinking water was found to be suitable for toxicity tests. German Drinking Water Regulation (Trinkwasserveordnung, Bundesgesetzblatt December 05, 1990) served as a guideline for maximum tolerance contaminants.
pH	7.7-8.1	
Dissolved oxygen	5.1-8.5 mg/L	
Total Organic carbon	Not reported	
Particulate Matter	Not reported	
Metals	Not reported	
Pesticides	Not reported	
Chlorine	Not reported	
Temperature	22-23 $\pm$ 1°C	The concentrations of dissolved oxygen were maintained >60% of saturation at the test temperature of 23°C with the exception of the two test vessels which decreased to 59% saturation at 48 hours.

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Parameter	Details	Remarks *Criteria*
Biomass loading rate	0.8 g fish/L water	*Recommended static conditions are ≤ 0.8 g/L at ≤ 17°C and ≤ 0.5 g/L at > 17°C. Recommended flow-through conditions are ≤ 1 g/L/day. OECD recommends a maximum of 1 g fish/L for static and semi-static, while higher rates are recommended for flow-through.*
Test concentrations Nominal: Measured: TWA (reviewer calculated):	 0 and 120 mg a.i./L <0.001 and 108 mg a.i./L <0.001 and 108 mg a.i./L	TWA concentrations were reviewer-calculated using Excel software (worksheet copied in Appendix I).
Solvent (type, percentage, if used)	N/A	*The solvent should not exceed 0.5 ml/L for static tests or 0.1 ml/L for flow-through tests; OECD recommends that the solvent not exceed 100 mg/L.*
Lighting	16 hours light:8 hours dark; Approx. 36-191 Lux	Light intensity was determined at regular intervals at the surface of the aquaria. *The recommended photo period is 16 hours of light and 8 hours of dark with a 15-30 minute transition period. OECD recommends a photo period of 12 -16 hours.*
Feeding	Fish were not fed during the definitive test	*Fish should not feed during the study.*
Recovery of chemical Frequency of determination Level of quantization Level of detection	 0, 48 and 96 hours 0.001 mg/L Not reported	An analytical method for the determination of the test substance in the test water was developed by the Ecology and Environmental Analytics Agricultural Center Limburgerhof of BASF Aktiegesellschaft, Ludwigshafen, Germany. The analysis were carried out as a separate study at the test facility Agricultural Center Limburgerhof, Ecology and Environmental Analytics of BASF Aktiegesellschaft, Ludwigshafen, Germany. The study was carried out in compliance with the Principles of GLP.